IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION
CIVIL DOCKET NO.: 5:05CV200

PATRICIA FAULISE, DEC., by and through Personal Representative, JOE FAULISE, Husband,	)	
Plaintiff,	)	
	)	**ORDER**
vs.	)	
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,	)	
Defendant.	)	

THIS MATTER is before the Court on Defendant "Smithkline Beecham Corporation's Motion for Summary Judgment Based On Plaintiff's Failure to Comply with North Carolina's Statute of Limitations and Statute of Repose" and Brief in Support of Motion for Summary Judgment, both filed November 22, 2005. [Documents ## 10,11]. On December 30, 2005, Plaintiff filed her Response to Defendant's Motion for Summary Judgment. [Document # 13]. Defendant filed its Reply in Support of Its Motion for Summary Judgment on January 11, 2006. [Document # 14].[1] This Motion is now ripe for disposition by the Court.

Having carefully considered the arguments, the record, and the applicable authority, for the below-stated reasons the Court will grant Defendant's Motion for Summary Judgment.

I. FACTUAL AND PROCEDURAL HISTORY

For purposes of this Motion for Summary Judgment, the Court accepts the following facts

[1]The Court notes that Defendant filed its exhibits in support of the Motion for Summary Judgment, as well as its Reply under seal, pursuant to the Protective Order entered by the Court on September 15, 2005.

taken in the light most favorable to Plaintiff as true. *See Anderson v. Liberty Lobby*, 477 U.S. 242, 255 (1986).

In 1994, Patricia Faulise ("Ms. Faulise") began receiving injections of Imitrex® from her physician for migraine headaches.[2] (Compl. ¶ 21). Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline[3] ("Defendant" or "GlaxoSmithKline") is responsible for researching, developing, manufacturing, testing, packaging, and distributing Imitrex®. (*Id.* ¶ 7). In 1995, Ms. Faulise began home injections of Imitrex® in doses of six (6) milligrams each. (*Id.* ¶ 21). In February of 1997, Ms. Faulise began taking 25 milligram tablets of Imitrex®, as well as using the injections. (*Id.*). In December 1997, Ms. Faulise's physician prescribed five (5) milligrams of Imitrex® nasal spray. (*Id.*). However, an Imitrex® representative recommended that the doctor prescribe a 20 milligram dose of nasal spray, so Ms. Faulise's prescription was increased. (*Id.*). Ms. Faulise continued taking Imitrex® until April 3, 1998. (*Id.*).

On April 3, 1998, Ms. Faulise took one 25 milligram Imitrex® tablet in the morning and another tablet in the evening. (Pattishall Aff. Exh. pp. 59-60). Later that evening, Ms. Faulise experienced a sudden onset of back pain, weakness, chest and heart pain, and difficulty walking. (Compl. ¶ 21; Pattishall Aff. Exh. pp. 59-60). Ms. Faulise was taken to the hospital, where she experienced cardiac arrest and was diagnosed with myocardial infarction due to cardiac spasm. (Compl. ¶ 21; Pattishall Aff. Exh. p. 59-60, 64). After her heart attack, Ms. Faulise was advised by her physician to discontinue using Imitrex®. (Compl. ¶ 21).

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[2]Imitrex® is generically known as sumatriptan succinate. (Compl. ¶ 1).

[3]GlaxoSmithKline is a successor in interest to SmithKline Beecham Corporation, a British Corporation and SmithKline Beecham Corporation, its wholly owned subsidiary, a Pennsylvania corporation. (Compl. ¶ 2).

GlaxoSmithKline maintains a Global Clinical Safety and Pharmacovigilance department ("GCSP"). (Pattishall Aff. ¶ 6). "Pharmacovigilance involves scientific activities relating to the detection, assessment, understanding, and prevention of adverse events or other drug-related problems, including spontaneous reports and preclinical, clinical, epidemiological, pharmacoepidemiological, and pharmacogenetic studies." (*Id.* ¶ 8). Unsolicited reports involving patients who experience adverse events in the course of a routine clinical practice with marketed drugs are titled "spontaneous" reports. (*Id.* ¶ 9). Upon receipt of a spontaneous report, scientific and administrative staff at GlaxoSmithKline prepare a case narrative describing the reported adverse event. (*Id.* ¶ 12). Pursuant to the Food and Drug Administration ("FDA") regulations, all spontaneous reports of serious, unexpected adverse events must be reported on an expedited basis to the FDA on a MedWatch Report. (*Id.* ¶ 15).

On February 19, 2001, Ms. Faulise reported her heart attack to GlaxoSmithKline sales representative S. Hayworth Szymborski. (Pattishall Aff. ¶ 23; Exh. p. 64). Ms. Faulise further advised Ms. Szymborski that on April 3, 1998, she suffered cardiac arrest, an enlarged heart, and an ejection fraction of approximately thirty to thirty-five percent (30%-35%). (Pattishall Aff. ¶ 23; Exh. p. 64). Ms. Faulise advised the GlaxoSmithKline sales representative that she was taking 25 milligram Imitrex® tablets. (*Id.*). In response to Ms. Faulise's report, GlaxoSmithKline created an initial MedWatch Report for submission to the FDA. (Pattishall Aff. ¶ 23; Exh. pp. 59-60).

On February 27, 2001, GlaxoSmithKline sent Ms. Faulise a letter, asking her to review the Adverse Event Report form, which reflected the information she provided to GlaxoSmithKline, and to advise GlaxoSmithKline of any further details not contained on the

form. (Pattishall Aff. ¶ 26; Exh. p. 54). GlaxoSmithKline also asked Ms. Faulise for her consent to allow the Company to obtain additional information from Ms. Faulise's physician. (*Id.*).

On April 3, 2001, GlaxoSmithKline sent a follow-up letter to Ms. Faulise, asking her to review the information contained on the Adverse Event Report form and requesting permission to contact her physician to obtain additional information. (Pattishall Aff. ¶ 27; Exh. p. 50). On April 4, 2001, Ms. Faulise completed the Adverse Event Report form and indicated, among other things, that there was an "almost certain" relationship between her use of Imitrex® and her heart attack.[4] (Pattishall Aff. ¶ 28; Exh. pp. 46-48). Ms. Faulise also signed an Authorization for GlaxoSmithKline to gather further information from her physician, Daniel Koehler, who is a doctor of osteopathic medicine ("D.O."). (Pattishall Aff. ¶ 29; Exh. p. 49). As a result of the information provided by Ms. Faulise, GlaxoSmithKline updated her Adverse Event Report form for submission to the FDA. (Pattishall Aff. ¶ 31; Exh. pp. 44-45).

On April 30, 2001, Daniel Koehler, D.O. revised the Adverse Event Report form that GlaxoSmithKline sent to him regarding Ms. Faulise. (Pattishall Aff. ¶ 33; Exh. pp. 36-38). Among other things, Dr. Koehler indicated an "almost certain" relationship between Ms. Faulise's use of Imitrex® and her heart condition. (*Id.*).

Subsequent to her April 3, 1998 heart attack, and despite discontinuing use of Imitrex®, on November 29, 2001, Dr. Daniel Koehler advised Ms. Faulise that she needed a heart transplant. (Compl. ¶ 21). On February 15, 2002, Richard Lutzel, Esq., sent a letter to

[4]The Adverse Event Report form allowed Ms. Faulise to indicate whether the relationship between her heart condition and her use of Imitrex® was "almost certain," "probable," "possible," "unlikely," or "not related." (Pattishall Aff. ¶ 28; Exh. pp. 46-48). As discussed, Ms. Faulise chose the highest relationship - "almost certain" - to describe the correlation between her heart condition and use of Imitrex®.

GlaxoSmithKline, advising the Company that his law firm, Lutzel and Associates, PLLC, represented Patricia and Joseph Faulise for damages resulting from Ms. Faulise's use of Imitrex®, and indicating that Ms. Faulise was in need to a heart transplant as "a direct result" of her use of Imitrex®. (Pattishall Aff. ¶ 36; Exh. p. 30). However, before she was able to obtain a heart transplant, Ms. Faulise died of ischemic cardiomyopathy on April 17, 2004. (Compl. ¶ 21).

On March 24, 2005, Plaintiff filed a Complaint in the Iredell County Superior Court Division, alleging the following causes of action: (1) strict product liability (failure to warn); (2) strict product liability; (3) negligence; (4) breach of express warranty; (5) breach of implied warranty; (6) unjust enrichment; and (7) loss of consortium. On May 4, 2005, GlaxoSmithKline removed the action to this Court.

II. DISCUSSION

Defendant now asks the Court to grant summary judgment, contending that Plaintiff's claims are barred under North Carolina's Statute of Limitations and by North Carolina's Statute of Repose.

A. Standard of Review

Rule 56(c) of the Federal Rules of Civil Procedure permits the entry of summary judgment where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). A genuine issue exists only if "the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Anderson*, 477 U.S. at 248. But the party opposing summary judgment may not

rest upon mere allegations or denials, and a "mere scintilla of evidence" is insufficient to overcome summary judgment. *Id.* at 249-50. Moreover, when the movant supports its motion for summary judgment by affidavits, the adverse party may not rest upon the mere allegations or denials of their pleading, but the adverse party's response must be supported by affidavits or as otherwise provided by Rule 56 and must set forth specific facts showing that there is a genuine issue for trial. FED. R. CIV. P. 56(e).

Courts, in considering motions for summary judgment, view the facts and inferences in the light most favorable to the party opposing the motion. *Anderson*, 477 U.S. at 255; *Miltier v. Beorn*, 896 F.2d 848 (4th Cir. 1990); *Cole v. Cole*, 633 F.2d 1083 (4th Cir. 1980). Summary judgment is thus proper where "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there [being] no genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal quotations omitted).

B. Statute of Limitations

Defendant argues that North Carolina's three year statute of limitations, which begins to run when the injury occurs, bars Plaintiff's claims. (Def. Mem. in Supp. pp. 13-20). Defendant states that at the latest, the statute of limitations on Plaintiff's claims began to run by April 4, 2001, when Ms. Faulise revised the Adverse Event Report form, indicating an "almost certain" relationship between her heart attack and her use of Imitrex®. (*Id.* pp. 17-18). Defendant further maintains that since Plaintiff's personal injury claims are barred by the statute of limitations, the wrongful death action is also barred. (*Id.* pp. 19-20).

In response, Plaintiff argues that while Ms. Faulise suffered a number of injuries as a

result of taking Imitrex®, her congestive heart failure was not discovered until August of 2002.[5] (Pl. Resp. pp. 5-6). According to Plaintiff, since the lawsuit was filed on March 24, 2005, the statute of limitations is not a bar to Plaintiff's claims based on Ms. Faulise's congestive heart failure.[6] (*Id.* p. 7).

"In general, 'the question of whether a cause of action is barred by the statute of limitations is a mixed question of law and fact.'" *First Investors Corp. v. Citizens Bank, Inc.*, 757 F. Supp. 687, 689 (W.D.N.C. 1991) (quoting *Pembee Mfg. Corp. v. Cape Fear Constr. Co.*, 313 N.C. 488, 491, 329 S.E.2d 350 (1985)). Where the statute of limitations is properly pleaded, and the facts with reference to it are not in conflict, the issue is a matter of law, and summary judgment is appropriate. *Soderlund v. Kuch*, 143 N.C. App. 361, 366, 546 S.E.2d 632, 636 (2001). "'Once a defendant has properly pleaded the statute of limitations, the burden is then placed upon the plaintiff to offer a forecast of evidence showing that the action was instituted within the permissible period after the accrual of the cause of action.'" *Soderlund*, 143 N.C. App. at 366, 546 S.E.2d at 636 (quoting *Waddle v. Sparks*, 331 N.C. 73, 85-86, 414 S.E.2d 22, 28-29

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[5]In his response, Plaintiff admits that a number of injuries suffered by Ms. Faulise are time barred, but further argues that at least one of her injuries, congestive heart failure, was not discovered until August of 2002, and, therefore, is not barred by the statute of limitations. Notably, however, Plaintiff alleges in the Complaint that on April 3, 1998, Ms. Faulise experienced a heart attack and accompanying chest pain, heart pain and dizziness as a result of her use of Imitrex®. (Compl. ¶ 21). However, nowhere in the Complaint does Plaintiff mention Ms. Faulise being diagnosed with congestive heart failure.

[6]The Court notes that in the Response, Plaintiff does not provide any citations to the record, nor does Plaintiff support his allegations with "pleadings, depositions, answers to interrogatories, and admissions on file," as required by Rule 56(c) of the Federal Rules of Civil Procedure. In order to overcome a motion for summary judgment, "the non-moving party must present facts, in proper form - conclusions of law will not suffice. . . . The facts must be material, and of substantial nature; not fanciful, frivolous, gauzy, spurious, irrelevant, gossamer inference, conjectural, speculative, nor merely suspicions." *Lindsay v. Public Serv. Co. of N.C., Inc.*, 725 F. Supp. 278, 280 (W.D.N.C. 1989). Plaintiff's Response fails to meet these requirements. Moreover, since Defendant supported its Motion for Summary Judgment with an affidavit, Plaintiff cannot rest upon mere allegations or denials, but must have supported the Response with affidavits or as otherwise permitted by Rule 56. FED. R. CIV. P. 56(e). Plaintiff provided no such supporting documentation.

(1992)).

Under North Carolina law, a three year statute of limitations applies to various causes of action. N.C. GEN. STAT. § 1-52. For example, a breach of warranty claim is subject to the three year statute of limitations. N.C. GEN. STAT. § 1-52(1). Moreover, an action for any "injury to the person or rights of another, not arising on contract" and not enumerated in Section 1-52, is also governed by a three year limitations period. N.C. GEN. STAT. § 1-52(5). Here, the majority of Plaintiff's claims fall within North Carolina's three year statute of limitations period.[7] Thus, the next issue is the date on which the limitations period began to run.

"[A]s soon as the injury becomes apparent to the claimant or should reasonably become apparent, the cause of action is complete and the limitation period begins to run." *Pembee*, 313 N.C. at 493, 329 S.E.2d at 354 (citing *Matthieu v. Gas Co.*, 269 N.C. 212, 152 S.E.2d 336 (1967)). However, the discovery statute tolls the running of a statute of limitations until the plaintiff discovers or should have discovered the injury. *Soderlund*, 143 N.C. App. at 369, 546 S.E.2d at 638 (citing *Black v. Littlejohn*, 312 N.C. 626, 642, 325 S.E.2d 469, 480 (1985)). With regard to personal injury, a cause of action ". . . shall not accrue until bodily harm to the claimant . . . becomes apparent or ought reasonably to have become apparent to the claimant, whichever event first occurs." N.C. GEN. STAT. § 1-52(16). "'The primary purpose of N.C. Gen. Stat. § 1-52(16) is that it is intended to apply to plaintiffs with latent injuries.'" *Soderlund*, 143 N.C. App. at 370, 546 S.E.2d at 638 (citing *Robertson v. City of High Point*, 129 N.C. App. 88, 91, 497 S.E.2d 300, 302 (1998), *disc. rev. denied*, 351 N.C. 370, – S.E.2d – (2000)).

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[7]Plaintiff does not dispute the applicability of North Carolina's three year statute of limitations to the claims alleged in the Complaint. (Pl. Resp. pp. 5-7). The Court discusses in more detail below the one claim asserted by Plaintiff that has a two year statute of limitations - the wrongful death claim. (*See* infra pp. 10-11).

Although Section 1-52(16) protects a plaintiff in the case of a latent defect by providing that a cause of action does not accrue until the plaintiff becomes aware or should have become aware of the existence of the injury, "'[a]s soon as the injury becomes apparent to the claimant or should reasonably become apparent, the cause of action is complete and the limitation period begins to run.'" *Soderlund*, 143 N.C. App. at 370, 546 S.E.2d at 638 (quoting *Pembee*, 313 N.C. at 493, 329 S.E.2d at 354). Notably, for purposes of the running of the statute of limitations, "[i]t does not matter that further damage could occur; such further damage is only aggravation of the original injury.'" *Pembee*, 313 N.C. at 493, 329 S.E.2d at 354 (citing *Matthieu v. Gas Co.*, 269 N.C. 212, 152 S.E.2d 336).

In the instant case, as described above, Ms. Faulise had a heart attack on April 3, 1998, and as of that date, her doctor advised her to discontinue using Imitrex®. (Compl. ¶ 21). Then, on February 19, 2001, Ms. Faulise reported her heart attack to GlaxoSmithKline sales representative S. Hayworth Szymborski. (Pattishall Aff. ¶ 23; Exh. p. 64). Ms. Faulise advised the GlaxoSmithKline sales representative that she was taking 25 milligram Imitrex® tablets. (*Id.*). Subsequently, on April 4, 2001, Ms. Faulise completed the Adverse Event Report form, as requested by GlaxoSmithKline, and indicated, among other things, that there was an "almost certain" relationship between her use of Imitrex® and her heart attack. (Pattishall Aff. ¶ 28; Exh. pp. 46-48).

It is likely that, by April 3, 1998, when Ms. Faulise suffered a heart attack and was advised to discontinue taking Imitrex®, Ms. Faulise knew or should have known that she suffered injury as a result of taking Imitrex®. Moreover, even if by April 13, 1998, Ms. Faulise

did not recognize a correlation between her heart condition and taking Imitrex®, by February 19, 2001, when she contacted GlaxoSmithKline and advised the Company of her heart condition, it is likely Ms. Faulise knew or should have known that she suffered injury as a result of taking the medicine.[8] However, construing the facts in the light most favorable to Plaintiff, the Court will presume that it was not until April 4, 2001, when Ms. Faulise advised GlaxoSmithKline that there was an "almost certain" relationship between her heart attack and her use of Imitrex®, that Ms. Faulise knew or should have known that she suffered injury from taking Imitrex®. In that event, in order to meet North Carolina's three year statute of limitations, Ms. Faulise had to file her lawsuit against Defendant on or before April 4, 2004. However, Plaintiff did not file a lawsuit on behalf of Ms. Faulise until March 24, 2005.

Although Plaintiff contends that Ms. Faulise's congestive heart failure was not discovered until August 2002, North Carolina law is clear that the worsening of Ms. Faulise's condition does not create a new limitations period. In sum, "as soon as plaintiff's injury became apparent, or ought reasonably to have become apparent, [her] cause of action accrued. . . . The fact that further damage which plaintiff did not expect was discovered does not bring about a new cause of action, it merely aggravates the original injury." *Pembee*, 313 N.C. at 493-94, 329 S.E.2d at 354 (citing *Matthieu*, 269 N.C. 212, 152 S.E.2d 336).

Additionally, since Plaintiff's personal injury claims are barred by the three year statute of limitations, the wrongful death cause of action is also barred. Although wrongful death claims have a two year statute of limitation, and Ms. Faulise died on April 17, 2004, "whenever the

[8]The Court notes that the most likely reason Ms. Faulise contacted GlaxoSmithKline on February 19, 2001, and advised the Company of her medical condition was due to her belief in a correlation between her heart attack and taking Imitrex®.

decedent would have been barred, had [she] lived, from bringing an action for bodily harm because of the provisions of G.S. 1-15(c) or 1-52(16), no action for h[er] death may be brought." N.C. GEN. STAT. § 1-53(4); *see also Dunn v. Pacific Employers Ins. Co.*, 332 N.C. 129, 134, 418 S.E.2d 645, 648 (1992) (noting that Section 1-53(4) provides a limitation defense to a wrongful death action when the claim for injuries caused by the underlying wrong had become time-barred during the decedent's life). Since Ms. Faulise failed to bring her claims for personal injury on or before April 4, 2004, her claims were time-barred while she was still living. Consequently, Plaintiff's wrongful death claim on behalf of Ms. Faulise is also barred.

In sum, since Plaintiff failed to institute this lawsuit within three years of when Ms. Faulise discovered or should have discovered her injuries - April 4, 2001 - and since Ms. Faulise's claims were barred prior to her death on April 17, 2004, Defendant is entitled to summary judgment on Plaintiff's claims.[9]

III. CONCLUSION

IT IS, THEREFORE, ORDERED that Defendant's Motion for Summary Judgment is hereby **GRANTED**.

Signed: August 2, 2006

Richard L. Voorhees
United States District Judge

[9]Since the Court concludes that Plaintiff's lawsuit is barred by the applicable statute of limitations, the Court will not address Defendant's argument that Plaintiff's claims are further barred by North Carolina's Statute of Repose.